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10/562,633	06/09/2006	Todd Maibach	14PS-129581	8600

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/562,633	MAIBACH, TODD
	Examiner	Art Unit
	LAKSHMI CHANNAVAJJALA	1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-104* is/are pending in the application.

4a) Of the above claim(s) *1-17,20-35 and 37-104* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *18, 19 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and remarks dated 5-11-11 is acknowledged.

Claims 1-104 are pending. Claims 18, 19 and 36 have been elected and examined previously.

Claims 1-17, 20-35 and 37-104 have been withdrawn as being non-elected.

The following rejections of record have been maintained:

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6596298 to Leung et al in view of US 5,288,497 to Stanley et al (Stanley) and US 6139847 to Chobanian.

Alternatively,

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6596298 to Leung et al in view of US 2007/0184093 to Hang, US 5,288,497 to Stanley et al (Stanley) and US 6139847 to Chobanian.

Alternatively,

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,288,497 to Stanley et al (Stanley) in view of any one of US 6,596,298 to Leung et al in view of US 2007/0184093 to Hang, and further in view of US 6139847 to Chobanian.

Leung et al. teach edible films that preferably include pullulan, antimicrobially effective amounts of thymol, methyl salicylate, eucalyptol, menthol; and contain pharmaceutical actives (Abstract, col. 2 summary of the invention). The film more preferably comprises pullulan as a film forming agent in amounts of 45% to 70% (col. 5, L 1-10, col. 11 and examples in col. 17-18) that reads on the claimed amounts of pullulan and further Leung suggests incorporating a number of medicaments or pharmacological agents (col. 12). Leung does not teach nitroglycerin and combination of nitroglycerin with other cardiovascular agents.

With respect to the newly added amounts of water, Leung teaches that the film contains 3% to 8% water in col. 11, lines 18-24.

Hang teaches soluble films comprising a soluble polymer and a strengthening polymer (0017) for delivery of emergency medical care active agents such as nitroglycerin (0019). For the soluble films, Hang preferably teaches pullulan (0030). Hang as well as Leung fails to exemplify a pullulan with nitroglycerin, particularly in the claimed amounts.

Leung or Hang fail to teach an embodiment containing nitroglycerin, in the claimed amounts, and lacks the combination of nitroglycerin with other cardiovascular agents.

Stanley teaches orally dissolvable medicaments wherein the composition is capable of absorption through the mouth, pharynx and esophagus (abstract), in particular for administering fast acting and potent drugs (col . 5, L 19-25). The medicament of Stanley involves a dissolvable matrix made of carbohydrates, fats or

proteins (col. 5, L 43-52). For the active agents, Stanley teaches nitroglycerin in an amount of 0.4 to 1.0 mg (table 2, l 30-45), which is within the claimed 0.01 mg-100 mg of nitroglycerin. Stanley lacks pullulan film and the combination of cardiovascular agents claimed.

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to incorporate 0.4 to 1.0 mg of nitroglycerin of (Stanley) in the fast dissolving oral film containing pullulan of Leung or Hang because Stanley teaches the above amounts of nitroglycerin as appropriate for incorporating in a medicament matrix that enables fast absorption through mucosal membranes of oral cavity and overcome the disadvantages of oral administration by other mechanisms such as frequent swallowing of pills, first pass effect, delay between the administration of tablets etc. Alternatively, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to prepare nitroglycerin dissolvable films with 0.4 to 1.0 mg of nitroglycerin of (Stanley) in the fast dissolving oral film containing pullulan of Leung or Hang because both Leung and Hang teach pullulan films for fast dissolution and for the delivery of oral active agents and Hang particularly teaches the films for nitroglycerin delivery. Further, a skilled artisan would have been able to employ combinations of medicaments for treating cardiovascular conditions with nitroglycerin of Stanley in the pullulan films of Hang or Leung, with an expectation to at least achieve an additional protective effect if not a synergistic effect, as suggested by Chobanian et al (abstract, col. 3-4).

Response to Arguments

2. Applicant's arguments filed 5/11/11 have been fully considered but they are not persuasive.

Applicants state that solely in the interest of advancing prosecution, and without agreeing with the propriety of the Examiner's rejection or disclaiming any subject matter to which they are entitled, Applicant has amended claim 18. Applicants argue that the cited references, Stanley, Chobanian Leung and Hang alone or in combination, do not teach or suggest each and every element of the presently-claimed invention. Specifically, the references, singly, or in combination, do not teach or suggest a consumable film including about 0.01 mg to about 100 mg nitroglycerin in a single layer consumable film including about 40 to about 80 wt % pullulan, water in an amount from about 3 to about 8 wt %, and at least one additional pharmaceutical agent, wherein the consumable film provides rapid transmucosal delivery of nitroglycerin to a patient. It is argued that there is no teaching or suggestion to combine the cited references and a skilled artisan would have no reasonable expectation of success. Applicants argue that Hang relates to producing "very strong films" (Paragraph [0032]) by adding strengthening polymers that "decrease the water solubility and total soluble matter of the end product" (see, e.g., Paragraph [0033]). Specifically, Hang adds a second strengthening polymer to a soluble polymer that is provided in very small concentrations, i.e. concentrations of "0.1% to 5%." Paragraph [0029] that is far less amounts than the claimed amounts of Pullulan. It is further argued that Stanley relates to lollipops that comprise drugs. See Stanley, Figs. 1-8. Stanley does not teach or

suggest the use of thin films of any kind. The "dissolvable matrix made of carbohydrates, fats or proteins" in a lollipop does not have any relation to the consumable film with "about 40 to about 80 wt % pullulan" as presently claimed. Further, it is argued that the Examiner's argument that Stanley demonstrates "orally dissolvable medicaments wherein the composition is capable of absorption through the mouth, pharynx and esophagus," apparently for nitroglycerin, is overstated. Stanley merely provides a laundry list of 72 drugs which includes nitroglycerin; there is no teaching or suggestion whatsoever regarding the use or utilization of nitroglycerin in thin films comprising about 40 to about 80 wt % pullulan water, much less in the described lollipops. Merely providing a laundry list of drugs (no matter the amounts) that may be included in lollipops, does not demonstrate to one of ordinary skill that there would have a reasonable expectation of success of making the invention as presently claimed. Applicants argue that Leung and Chobanian fail to remedy these glaring deficiencies of Hang and Stanley as these references do not teach or suggest the limitation of a consumable film which provides rapid transmucosal delivery of nitroglycerin to a patient. Neither Leung nor Chobanian teach or suggest any range or amount of nitroglycerin.

Applicants' arguments are not persuasive because the newly added limitations of the amounts of Pullulan and water are taught by Leung reference. For this reason, the argument regarding the teachings of Hang that they lack the claimed amounts of pullulan is not persuasive because the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or

all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this regard, Leung teaches the claimed amounts of pullulan and water. Hang has been cited only to show that medicaments can be employed with pullulan films. Further, Stanley has been cited only for the teaching that nitroglycerin is a medicament that can be absorbed through mouth, pharynx and not for the film. Thus, a skilled artisan would have employed any medicament including nitroglycerin (of Stanley or Hang) in the pullulan film forming composition of Leung with an expectation to provide fast absorption through mucosal membranes of oral cavity and overcome the disadvantages of oral administration by other mechanisms such as frequent swallowing of pills, first pass effect, delay between the administration of tablets etc.

The following is a new rejection in light of the amendment:

Claim Rejections - 35 USC § 112

3. Claims 18, 19 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Instant claim recites the new limitation “about 40 to about 80 wt % pullulan, water in an amount from about 3 to about 8 wt %”. A close review of the instant description

does not reveal any support for the new limitation of from about 3 to about 8 wt %. It is noted that page 11 of the instant description only states that the film may comprise water but without specifying the amounts. The cited paragraphs [054] and [056] only recite pullulan but not water. In fact, the claimed specification fails to teach any amounts of water in the claimed compositions. This is a new matter rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKSHMI CHANNAVAJJALA whose telephone number is (571)272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611